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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,588	04/17/2000	LARRY S. MILLSTEIN	LAMILL2	2048

23599 7590 09/29/2004

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EXAMINER	
TRAN, MY CHAU T	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/529,588	MILLSTEIN, LARRY S.	
	Examiner	Art Unit	
	MY-CHAU T TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-55,57-67,69,71,73,74,76-78,94-97,100-105,107-131,133-135,137 and 138* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-55,57-67,69,71,73,74,76-78,94-97,100-105,107-131,133-135,137 and 138* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicant's response filed 7/23/2004 is acknowledged and entered.

2. Claims 106, 132, and 136 were canceled and Claims 48, 57, 111, 121, and 129 were amended by the examiner amendment filed on 3/25/2003.

3. Claims 56, 68, 70, 72, 75, 79-93, 98-99 were canceled; Claims 48-55, 57-58, 63-67, 69, 71, 73, 76, 78, and 95-97 were amended; and Claims 100-138 were added by the amendment filed on 1/2/2003.

4. Claims 48, 50, 52, 64, 66, 71, 76, 77, and 79 were amended and Claims 94-99 were added by the amendment filed on 7/10/2002.

5. Claims 1-47 were canceled and Claims 48-93 were added by the preliminary amendment filed on 3/8/2001.

6. Claims 48-55, 57-67, 69, 71, 73-74, 76-78, 94-97, 100-105, 107-131, 133-135, and 137-138 are pending.

7. Claims 48-55, 57-67, 69, 71, 73-74, 76-78, 94-97, 100-105, 107-131, 133-135, and 137-138 are treated on the merit in this Office Action.

Maintained Rejections

Claim Rejections - 35 USC § 102

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 48-53, 55, 57-62, 71, 73-74, 76-78, 94, 96-97, 100-103, 105, 117-121, 124-131, 133-135, 137, and 138 are rejected under 35 U.S.C. 102(a) as being anticipated by Stimpson (US Patent 6,037,186; *filed* 7/16/1997). *Note: This prior art was provided by applicant.*

Stimpson discloses "a method to produce arrays of compounds for concurrent testing" (Abstract; col. 3, lines 47-54; col. 4, lines 22-34). "Two formats are described using porous rods or porous sheet materials. In both cases, a bundle is formed by radial compression of the rods or spiral wrapping of the sheet. A sheath is applied to the bundle and arrays are cut as slabs. Each synthesis or application step to create an array element is used to fabricate multiple arrays." The array elements (array members) comprise biological compounds such as nucleic acid and proteins (col. 3, lines 47-51). The rods comprise materials such as glass, polystyrene, or polypropylene (col. 10, lines 16-49) (refers to claims 58-62 and 130-131). The array elements are attached to the rod (col. 4, lines 7-11) (lumen). The method disclosed a random synthesis of a number of compounds resulting in different array elements for each rod within a bundle of rods (col. 10, line 60 to col. 11, line 12) (refers to 'at least two array members are different from one

another). The thickness of the cut slabs is in the range of 0.2-1 mm thick (col. 12, lines 11-14) (refers to claims 69). The cutting is performed by either a microtome device or laser (col. 12, lines 12-17 and lines 42-54) (smooth planar cut). The array is use to carry out assay such as binding assay (col. 6, lines 8-36; col. 12, line 57 to col. 14, line 5). Therefore, the method of Stimpson is anticipated the presently claimed invention.

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 48-55, 57-67, 69, 71, 73-74, 76-78, 94-97, 100-105, 107-131, 133-135, and 137-138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel et al. (US Patent 5,690,894) and Stimpson (US Patent 6,037,186).

Pinkel et al. disclose a method "for fabricating biosensors comprising a plurality of biological "binding partners" (molecules that specifically bind other molecules to form a binding complex such as antibody-antigen, lectin-carbohydrate, nucleic acid-nucleic acid, biotin-avidin, etc.) linked to optical fibers" (col. 3, lines 2-7). The multiplicity of optical fibers is bundled together to form an optical fiber array (col. 3, lines 18-20). Further, a multiplicity of species of biological binding partner may be attached to each group as long as the multiplicity of species of biological binding partners attached to one fiber group is different than the multiplicity of species attached to the other fiber groups (col. 3, lines 37-43) (refers to 'at least two array members are

different from one another). The binding partner includes nucleic acids, antibodies, proteins, and lectins (col. 3, lines 13-17).

The method of Pinkel et al. does not expressly disclose that sectioning the bundle of target-strands.

Stimpson discloses "a method to produce arrays of compounds for concurrent testing" (Abstract; col. 3, lines 47-54; col. 4, lines 22-34). "Two formats are described using porous rods or porous sheet materials. In both cases, a bundle is formed by radial compression of the rods or spiral wrapping of the sheet. A sheath is applied to the bundle and arrays are cut as slabs. Each synthesis or application step to create an array element is used to fabricate multiple arrays." The array elements (array members) comprise biological compounds such as nucleic acid and proteins (col. 3, lines 47-51). The rods comprise materials such as glass, polystyrene, or polypropylene (col. 10, lines 16-49) (refers to claims 58-62 and 130-131). The array elements are attached to the rod (col. 4, lines 7-11) (lumen). The method disclosed a random synthesis of a number of compounds resulting in different array elements for each rod within a bundle of rods (col. 10, line 60 to col. 11, line 12) (refers to 'at least two array members are different from one another). The thickness of the cut slabs is in the range of 0.2-1 mm thick (col. 12, lines 11-14) (refers to claims 69). The cutting is performed by either a microtome device or laser (col. 12, lines 12-17 and lines 42-54) (smooth planar cut). The array is use to carry out assay such as binding assay (col. 6, lines 8-36; col. 12, line 57 to col. 14, line 5).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include sectioning the bundle of target-strands as taught by Stimpson in

the method of Pinkel et al. One of ordinary skill in the art would have been motivated to include sectioning the bundle of target-strands in the method of Pinkel et al. for the advantage of providing a three-dimensional array that behave like membrane composed of porous materials and conduct flow through (Stimpson: col. 3, lines 36-46). One of ordinary skill in the art would have reasonably expectation of success in the combination of Pinkel et al. and Stimpson because both Pinkel et al. and Stimpson disclose method of attaching of binding agent to a rod (Pinkel: col. 10, lines 13-20; Stimpson: col. 4, lines 7-11).

Response to Arguments

12. Applicant's arguments directed to the rejection under 35 USC 102(a) as being anticipated by Stimpson (US Patent 6,037,186; *filed 7/16/1997*) for claims 48-53, 55, 57-62, 71, 73-74, 76-78, 94, 96-97, 100-103, 105, 117-121, 124-131, 133-135, 137, and 138 were considered but they are not persuasive for the following reasons.

Applicant contends that the method of Stimpson does not anticipate the presently claimed method because Stimpson does not disclose "structural members each of which has a lumen therethrough which is continuously enclosed thereby". Thus the method of Stimpson does not anticipate the presently claimed method.

Applicant's arguments are not convincing since the method of Stimpson does anticipate the presently claimed method.

First, the instant specification disclosure describes the bundle as a round hollow fiber such as glass (see pg. 16, lines 12-15; pg. 18, lines 31-34; pg. 19, lines 18-24; fig. 1) and the

lumen is the wall material of the bundle wherein the array members are immobilized (see pg. 22, lines 23-26). Stimpson disclose the rods of porous materials, which are compatible with a chemical synthesis or compound application step, i.e. compounds are immobilized on the porous material of the rod (col. 3, lines 47-48-66). The rods are formed from the processes similar to those used in producing hollow fiber membranes, i.e. the rods are hollow fibers (col. 3, line 66 to col. 4, line 3). Stimpson also discloses "*each rod is dipped or otherwise exposed to a unique binding agent to allow uniform attachment throughout its length (Z axis)*" (emphasis added). Thus the rods of porous materials of Stimpson anticipate the instant claimed bundle and lumen and teaches the limitation of "structural members each of which has a lumen therethrough, which is continuously enclosed thereby".

Second, figure 1A of Stimpson encompasses figures 1-4 of the instant application because figure 1A of Stimpson illustrates the rod bundle consisting of multiple rod elements, each with a biological binding properties imparted by immobilization of a suitable binding agent and the ends of the rod elements are exposed and regenerated during cutting of the bundle (col. 6, lines 39-45). Thus the rod bundle of Stimpson anticipates the instant claimed bundle and lumen and teaches the limitation of "structural members each of which has a lumen therethrough, which is continuously enclosed thereby".

Therefore, the method of Stimpson does anticipate the presently claimed method, and the rejection is maintained.

13. Applicant's arguments directed to the rejection under 35 USC 103(a) as being unpatentable over Pinkel et al. (US Patent 5,690,894) and Stimpson (US Patent 6,037,186) for claims 48-55, 57-67, 69, 71, 73-74, 76-78, 94-97, 100-105, 107-131, 133-135, and 137-138 were considered but they are not persuasive for the following reasons.

Applicant alleges that the method combination of Pinkel et al. (US Patent 5,690,894) and Stimpson (US Patent 6,037,186) is not obvious over the presently claimed method because neither Pinkel et al. nor Stimpson teaches "structural members each of which has a lumen therethrough which is continuously enclosed thereby". Thus the method combination of Pinkel et al. (US Patent 5,690,894) and Stimpson (US Patent 6,037,186) is not obvious over the presently claimed method.

Applicant's arguments are not convincing since the method combination of Pinkel et al. (US Patent 5,690,894) and Stimpson (US Patent 6,037,186) is obvious over the presently claimed method because Stimpson teaches "structural members each of which has a lumen therethrough which is continuously enclosed thereby" as discuss above with regard to the 102 rejection. Thus the method combination of Pinkel et al. (US Patent 5,690,894) and Stimpson (US Patent 6,037,186) is obvious over the presently claimed method.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
September 24, 2004

PADMASHRI PONNALURI
PRIMARY EXAMINER